

inadvertently omitted, additional time may be given to enable full compliance." For any other citations that the Examiner may consider "incomplete," no other information is currently available to the undersigned. Because the Examiner has the complete text of all of the references cited in the Information Disclosure Statement and the Examiner made no rejection over any of those references, Applicants presume that prosecution is now proceeding based on the prior art that the Examiner considers closest and most relevant to the claimed invention.

In the Office Action, the Examiner rejected claims 2-15 under 35 U.S.C. § 103 as being unpatentable over Gennaro in view of Stetz. Applicants respectfully traverse this rejection.

The rejection appears to rely primarily on Gennaro, which is a general reference related to aerosol packaging of pharmaceutical products. According to the Examiner, Gennaro discloses aerosol containers having "protective coatings" and valves analogous to those claimed. The Examiner relies on Stetz for the teaching of a metering device controlling discharge from aerosol cans, and concludes that it would have been obvious to one of ordinary skill in the art to use the metering device of Stetz in the aerosol cans disclosed by Gennaro.

The rejection should be reversed as Gennaro and Stetz fail to teach or suggest Applicants' claimed aerosol container system having a plastics coating located on the interior wall, where the plastics coating "inhibits the pharmaceutically active agent in the suspension from depositing thereon." Instead, Gennaro only states in general terms that a "protective coating" may prevent water and other corrosive materials from attacking tin containers, and that such a coating may make aluminum containers less reactive. See Gennaro, page 1670. Gennaro remains silent regarding the selection of coatings for the container that will inhibit the deposition of a pharmaceutically active agent thereon.

Stetz fails to remedy Gennaro's deficiency as Stetz makes no mention of any coating for the interior of an aerosol can. Accordingly, Stetz also fails to teach or suggest a coating that specifically inhibits the pharmaceutically active agent from depositing on the walls of the container.

It is well settled that, to sustain a rejection under section 103, the prior art must teach or suggest every limitation of an applicant's claims. MPEP § 2143.03. Although Gennaro exemplifies oleoresin, phenolic, vinyl, or epoxy coatings, Gennaro offers no indication as to whether such coatings may be used, or are intended to be used, to inhibit deposition of pharmaceutically active agents.

Further, the Examiner's vague and conclusory characterization of Gennaro's coatings as "analogous" to Applicants' claimed plastic coating does not adequately address Applicants' express recitation regarding inhibiting deposition of the pharmaceutically active agent. The mere fact that Gennaro's coatings, even if accurately considered "analogous," could have been modified to inhibit

the deposition of pharmaceutically active agents would not have made modification of Gennaro's coatings obvious unless the prior art would have suggested the desirability of such a modification. See, e.g., *In re Laskowski*, 10 U.S.P.Q.2d 1276, 1278 (Fed. Cir. 1987). Because Gennaro and Stetz do not even mention inhibiting deposition of pharmaceutically active agents, the alleged "analogous" nature of the coatings would have done nothing to motivate the skilled artisan to substitute a coating as recited in Applicants' claim 15 for Gennaro's coatings.

Applicants also disagree that Gennaro's coatings can be considered "analogous" to the claimed plastics coatings. As mentioned, Gennaro's coatings are designed to prevent water and other corrosive materials from attacking or reacting with a container. In contrast, Applicants' plastics coatings are selected to inhibit deposition of pharmaceutically active agent in a container. The prevention of corrosion in Gennaro is not analogous to and does not remotely suggest the desirability of preventing the deposition of pharmaceutically active agents in aerosol containers.

The rejection under section 103 is additionally flawed as it fails to consider Applicants' claimed invention as a whole. As mentioned, Applicants' claimed invention addresses a problem that occurs when fluorochlorohydrocarbon propellants are replaced with fluorohydrocarbon propellants. With fluorohydrocarbon propellants, pharmaceutically active ingredients tend to adhere to the inner surface of the aerosol container. Applicants' claims therefore recite the use of a plastics coating that inhibits deposition of pharmaceutically active agents thereon, in a system having a propellant gas free of fluorochlorohydrocarbons.

Gennaro and Stetz do not mention any problem related to the use of propellants free of fluorochlorohydrocarbons. Gennaro and Stetz do not mention any connection between deposition of pharmaceutically active agents and the use of propellants free of fluorochlorohydrocarbons. Gennaro and Stetz also do not identify any coating as inhibiting deposition of pharmaceutically active agents within the container. In this regard, Gennaro and Stetz clearly fail to support the bare conclusion that the "cited art is analogous because it . . . is reasonably pertinent to the particular problem with which the inventor is involved."

To the extent the Examiner takes the position that Gennaro's coatings *inherently* prevent the deposition of pharmaceutically active agent, the record does not support such a position. As explained by the Federal Circuit:

Inherency, however, may not be established by probabilities or possibilities. The mere fact that a certain thing may result from a given set of circumstances is not sufficient. If, however, the disclosure is sufficient to show that the natural result flowing from the operation as taught would result in the performance of the questioned function, it seems to be well settled that the disclosure should be regarded as sufficient.

*Continental Can Co. USA v. Monsanto Co.*, 20 U.S.P.Q.2d 1746, 1749 (Fed. Cir. 1991) (quoting *In re Oelrich*, 212 U.S.P.Q. 323, 326 (C.C.P.A. 1981)) [emphasis added].

Here, Gennaro only discusses the ability of his coatings to prevent water and corrosive ingredients from attacking tin surfaces of a container, and the coatings' ability to lessen reactivity of aluminum surfaces of the container. Gennaro does not state whether his coatings prevent deposition of a pharmaceutically active agent in the container. Without a disclosure in the prior art sufficient to show that prevention of the pharmaceutically active agent's deposition would invariably occur due to Gennaro's coatings, a proper case of inherency has not been presented. At best, an inherency argument based on the cited prior art would amount to an unsupported contention that Gennaro's coatings might inhibit deposition of pharmaceutically active agents in an aerosol container. As stated in *Continental Can*, however, inherency cannot be established by probabilities alone.

Claim 2 specifies that the plastics coating is polytetrafluoroethylene or perfluoroethylenepropylene. Claim 2 is separately patentable from claims 3-15 because prior art anticipating or rendering obvious claims 3-15 would not necessarily anticipate or render claim 2 obvious.

Gennaro and Stetz additionally fail to teach or suggest the plastics coatings recited in claim 2, i.e., a plastic coating that is polytetrafluoroethylene or perfluoroethylenepropylene. Again, all claim limitations must be taught or suggested to sustain a rejection under section 103. MPEP § 2143.03. Further, where the prior art may possibly disclose a genus embracing a claimed species, motivation to select the species does not necessarily exist to support a proper rejection under section 103. See *In re Baird*, 29 U.S.P.Q.2d 1550, 1552 (Fed. Cir. 1994). Conservatively, the oleoresin, vinyl, or epoxy coatings briefly mentioned by Gennaro embrace thousands of polymers. Gennaro and Stetz do not appreciate the problems associated with the replacement of fluorochlorohydrocarbons with alternative gas propellants. Consequently, nothing in either Gennaro or Stetz, alone or in combination, would have motivated the skilled artisan to select polytetrafluoroethylene or perfluoroethylenepropylene as coatings for use in an aerosol can. For at least these reasons, claim 2 is clearly patentable over Gennaro and Stetz.

In view of the foregoing, withdrawal of the rejection and early allowance of the application are respectfully requested.

If there are any fees due in connection with this communication, including any fees for an extension of time, such an extension is requested and the Commissioner is authorized to charge the fees to Deposit Account No. 19-0134 in the name of Novartis Corporation.

Respectfully submitted,



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